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22918	7590	09/20/2004	EXAMINER	
PERKINS COIE LLP			BARTON, JEFFREY THOMAS	
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MENLO PARK, CA 94026			1753	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/034,278	Applicant(s) KURNIK ET AL.	
	Examiner Jeffrey T. Barton	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>20020716, 20030303</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 20030627</u> . |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:
 - a. On page 6, at line 17, the term "sample-volume region" is used, though it appears "sample-loading region" was intended, based on the context.
 - b. On page 13, at line 6, the word "be" is used unnecessarily.Appropriate correction is required.

Claim Objections

2. Claim 9 is objected to because of its phrasing. In line 3, after the word "direction", please replace "than" with "as". Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1-8, and 14-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manz et al (US 6,280,589) in view of Křivánková et al.

Relevant to claim 1, Manz et al disclose a method for injecting a sample comprising a plurality of charged components and separating the components by electrophoresis in a microfluidic device (Column 1, lines 6-10; Column 2, lines 60-66), wherein said microfluidic device (Figures 1 and 3) includes a separation channel (22), having an upstream portion terminating in an upstream reservoir (R) and a downstream portion terminating in a downstream reservoir (W), sample and drain channels (23 and 24) intersecting the separation channel between the two channel portions at first and second junctions (25 and 26), respectively, and terminating in sample and drain reservoirs (S and D), respectively; and said device further includes electrodes in contact

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with the fluid in each said reservoir, including an upstream electrode, a downstream electrode, a sample electrode, and a drain electrode (Column 4, lines 4-10); the method comprising: a) placing into said separation channel, side channels and drain reservoir a first electrolyte solution (Column 3, line 66 - Column 4, line 3; Column 5, lines 35-38); b) placing into said sample reservoir the sample solution; c) creating a first voltage gradient between said sample electrode and said drain electrode, such that the charged components move into said separation channel (Column 5, lines 38-43); and d) placing at least one of said sample and drain electrodes in a floating state, and creating a second voltage gradient between said downstream and upstream electrodes, such that the charged components move through the separation channel and separate into discrete bands according to their electrophoretic mobilities. (Column 5, lines 48-58; "switched off" would correspond to the definition of "floating" given at page 11, lines 15-19 of the applicants' specification)

Also relevant to claim 1, Manz et al disclose the advantageousness of sample stacking within a prior art electrophoresis method. (Column 1, lines 48-51)

Relevant to claim 2, Manz et al disclose both sample and drain electrodes being in a floating state in step (d). (Column 5, lines 48-52)

Relevant to claim 3, Manz et al disclose a "pullback" method wherein during the separation step (i.e. step (d)) a voltage is applied between the upstream electrode and both the sample and drain electrodes, such that this voltage is in the same direction but of lower potential than that applied between the downstream and upstream electrodes. (Column 5, line 59 - Column 6, line 39)

Relevant to claims 4 and 5, Manz et al disclose the sample and drain channels intersecting the separation channels at either directly opposed junctions or at staggered junctions. (Column 4, lines 42-51)

Relevant to claim 6, Manz et al disclose the sample channel (23) being upstream of the drain channel (24). (Figure 3)

Relevant to claim 8, Manz et al disclose the upstream and downstream electrodes being in a floating state during step (c). (Column 5, lines 43-47)

Manz et al do not explicitly disclose a method in which the sample solution and background electrolyte are chosen such that the first and second electrolyte solutions each comprise an ion having lower mobility in an electric field than any of said charged components, and one or the other of said electrolyte solutions comprises an ion having higher mobility in an electric field than any of said charged components, nor do they explicitly disclose the injection step including sample stacking within a region of said separation channel. (Claim 1)

Relevant to claim 1, Křivánková et al disclose a method of sample stacking in capillary electrophoresis (Section 5, Sample induced transient ITP in CZE; further discussion on pages 31-33) in which the sample solution and background electrolyte are chosen such that the first (background) and second (sample) electrolyte solutions each comprise an ion having lower mobility in an electric field than any of said charged components (B in figure 24), and one or the other of said electrolyte solutions comprises an ion having higher mobility in an electric field than any of said charged components (A in figure 24)

Relevant to claims 14 and 15, Křivánková et al disclose within their method the use of negatively charged sample components and chloride as the higher mobility ion (Figure 23)

Relevant to claim 16, Křivánková et al disclose the use of imidazole as the low-mobility ion with negatively charged analytes. (Table 3)

Relevant to claims 17 and 18, Křivánková et al disclose the low-mobility ion having a concentration of 10 mM in a separation. (Figure 23)

Relevant to claims 19 and 20, Křivánková et al disclose analysis of charged sample components having a concentration of 0.1 μ M. (Figure 21)

Relevant to claims 21 and 22, Křivánková et al disclose the high-mobility ion having a concentration of 3-20 mM (Table 2), and also show experiments where its concentration ranges from 0-300 mM. (Figure 23)

Relevant to claim 23, Křivánková et al disclose a method in which only the first (i.e. leading) electrolyte solution comprises the high mobility ion. (Figure 18) This leading electrolyte also served as the background electrolyte for capillary zone electrophoresis.

Relevant to claim 24, Křivánková et al disclose a method in which only the second (i.e. sample) electrolyte solution comprises the high mobility ion. (Section 5)

Addressing claim 1, it would have been obvious to one having ordinary skill in that art at the time the invention was made to modify the method of Manz et al by using samples and electrolytes that would provide sample stacking upon injection and electric field application, as taught by Křivánková et al, because Manz et al described such

stacking as advantageous for electrophoretic separations. (Column 1, lines 48-51)

Furthermore, the use of electrokinetic injection as described in the method of Manz would lead to a degree of sample stacking within the separation channel in the injection step. (i.e. step (c) of the instant claim)

Addressing claim 3, it would also have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the method of Manz et al by only applying the "pullback" voltage to the side channels and reservoirs that have already been passed by the interface between the upstream end of the sample plug and background electrolyte, because it would minimize plug distortion and sample loss and also because there is no reason to prevent diffusion of sample into the sample plug itself. For example, in the case of staggered sample and drain channels (Sample channel being upstream, as in Figure 3), after injection it would be obvious to apply the pullback voltage only to the sample channel until the upstream end of the sample plug passes the junction (26) of the drain channel and the separation channel. This pause would correspond to the limitations of the instant claim.

Addressing claim 7, it would also be obvious to use the downstream side channel as the sample source, and the upstream side channel as the drain, because it would be equally effective in transferring sample into the separation channel, and in the case of positively charged analytes, it would facilitate sample stacking in the appropriate direction. (i.e. the direction of the electric field in the separation channel during injection would be the same as that during separation)

Addressing claims 14-24, examples of electrolytes and suitable concentrations from Křivánková et al, referenced to instant claims, are given above. Any would be obvious to use in a combined method.

7. Claims 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manz et al and Křivánková et al as applied to claim 1 above, and further in view of Ramsey. (US 6,342,142)

Manz et al and Křivánková et al disclose a combined method as described above in addressing claim 1.

Neither Manz et al nor Křivánková et al explicitly disclose a method wherein during step (c), a voltage gradient is created between said upstream and drain reservoirs, and between said downstream and drain reservoirs, in the same direction as that created between said sample and drain reservoirs (Claim 9); a method wherein during step (c), a voltage is applied to said drain electrode, and said sample, upstream and downstream electrodes are grounded (Claim 10); a method wherein the charged components are selected from the group consisting of nucleic acids, proteins, polypeptides, polysaccharides, and synthetic polymers (Claim 11); or a method of claim wherein said charged components comprise nucleic acids. (Claim 12)

Relevant to claims 9 and 10, Ramsey discloses an injection method wherein a voltage gradient is created between the upstream and drain reservoirs, and between said downstream and drain reservoirs, in the same direction as that created between

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said sample and drain reservoirs. (Column 5, lines 31-34; Figure 9; Column 7, line 63 - Column 8, line 24)

Relevant to claims 11 and 12, Ramsey discloses a method wherein the sample comprises nucleic acids. (Column 20, lines 35-36)

Addressing claim 9, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Manz et al and Křivánková et al by employing a “pinched” injection method, as taught by Ramsey, because it would prevent sample diffusion into the separation channel prior to application of a potential between the upstream and downstream electrodes.

Addressing claim 10, it would also be obvious to select the direction of the electric field based upon the charge of the capillary walls and specific capillary layout, in order to ensure electroosmotic flow in the desired direction.

Addressing claims 11 and 12, it would also be obvious to use the combined method of Manz et al and Křivánková et al to analyze samples comprising nucleic acids, because such capillary electrophoretic methods provide excellent resolution of mixtures of charged molecules. (See Manz et al, Background and Summary sections; numerous cited examples in Křivánková et al)

8. Claims 1 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuchs et al in view of Křivánková et al and Manz et al.

Fuchs et al disclose a method for injecting a sample comprising a plurality of charged components and separating the components by electrophoresis in a

microfluidic device (Column 4, lines 24-38), wherein said microfluidic device (Figures 1a and 1b) includes a separation channel (20), having an upstream portion terminating in an upstream reservoir and a downstream portion terminating in a downstream reservoir (Both reservoirs labeled 16), sample and drain channels intersecting the separation channel between the two channel portions at first and second junctions, respectively, and terminating in sample and drain reservoirs (24 and 26), respectively; and said device further includes electrodes in contact with the fluid in each said reservoir (Column 20, lines 61-63), including an upstream electrode, a downstream electrode, a sample electrode, and a drain electrode; the method comprising: a) placing into said separation channel, side channels and drain reservoir a first electrolyte solution (Column 20, lines 53-56; necessary for electrokinetic motion); b) placing into said sample reservoir the sample solution (Column 20, lines 56-59); c) creating a first voltage gradient between said sample electrode and said drain electrode (Column 15, lines 52-62; Column 20, lines 56-63), such that the charged components move into said separation channel; and d) creating a second voltage gradient between said downstream and upstream electrodes, such that the charged components move through the separation channel and separate into discrete bands according to their electrophoretic mobilities. (Column 16, lines 15-52)

Also relevant to claim 1, Fuchs et al disclose isotachophoretic concentration of a sample within their electrophoresis method. (Column 23, lines 48-53)

Relevant to claim 13, Fuchs et al disclose a method wherein the charged components comprise labeled molecules having distinct and characterized

electrophoretic mobilities (Column 23, lines 29-53; Column 26, lines 19-53), said molecules having been cleaved from molecular species with biological or chemical recognition properties in the course of a multiplexed chemical or biochemical assay (Column 23, line 29 - Column 24, line 47)

Fuchs et al do not explicitly disclose a method in which the sample solution and background electrolyte are chosen such that the first and second electrolyte solutions each comprise an ion having lower mobility in an electric field than any of said charged components, and one or the other of said electrolyte solutions comprises an ion having higher mobility in an electric field than any of said charged components, nor do they explicitly disclose the injection step including sample stacking within a region of said separation channel.

Fuchs et al also do not explicitly disclose placing at least one of said sample and drain electrodes in a floating state concurrently with application of the potential between upstream and downstream electrodes.

Křivánková et al disclose a method of sample stacking in capillary electrophoresis (Section 5, Sample induced transient ITP in CZE; further discussion on pages 31-33) in which the sample solution and background electrolyte are chosen such that the first (background) and second (sample) electrolyte solutions each comprise an ion having lower mobility in an electric field than any of said charged components (B in figure 24), and one or the other of said electrolyte solutions comprises an ion having higher mobility in an electric field than any of said charged components (A in figure 24)

Manz et al disclose placing at least one of said sample and drain electrodes in a floating state concurrently with application of the potential between upstream and downstream electrodes. (Column 5, lines 48-58)

It would have been obvious to one having ordinary skill in that art at the time the invention was made to modify the method of Fuchs et al by using samples and electrolytes that would provide sample stacking upon injection and electric field application, as taught by Křivánková et al, because it requires a simpler electrolyte system than typical isotachophoretic methods, and Fuchs et al described using isotachophoretic stacking within their method. (Column 23, lines 48-53) Furthermore, the use of electrokinetic injection would lead to a degree of sample stacking within the separation channel in the injection step. (i.e. step (c) of the instant claim)

It would also have been obvious to allow the electrodes in the sample and waste reservoirs to float after injection, as taught by Manz et al, because it provides the simplest method of injection. Additionally, with the staggered side channel geometry, it would also be obvious to allow the downstream (drain) side channel to float at least until the upstream end of the sample plug migrates past it, because there is no need to prevent sample diffusion into the sample plug itself. See the treatment of claim 3 in Paragraph 6 above.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-8 and 14-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 09/780,638 in view of Křivánková et al and Manz et al.

Claim 6 of Application No. 09/780,638 claims a method for injecting a sample comprising a plurality of charged components and separating the components by electrophoresis in a microfluidic device (Claim 1, lines 1-2 and step (d); Claim 6, lines 1-3 and 25-28), wherein said microfluidic device includes a separation channel, having an upstream portion terminating in an upstream reservoir and a downstream portion

terminating in a downstream reservoir, sample and drain channels intersecting the separation channel between the two channel portions at first and second junctions, respectively, and terminating in sample and drain reservoirs, respectively; and said device further includes electrodes in contact with the fluid in each said reservoir, including an upstream electrode, a downstream electrode, a sample electrode, and a drain electrode (Claim 1, lines 2-9; electrodes in the reservoirs would be necessary for application of voltage as described in the steps of the method); the method comprising: a) placing into said separation channel, side channels and drain reservoir a first electrolyte solution (Required for electrokinetic injection); b) placing into said sample reservoir the sample and a second electrolyte solution (Claim 1, step (a); Claim 6, lines 1-3 and 6-11), wherein one of said first and second electrolyte solutions comprises an ion having lower mobility in an electric field than any of said charged components (Claim 6, lines 22-24), and one or the other of said electrolyte solutions comprises an ion having higher mobility in an electric field than any of said charged components (Claim 6, lines 6-11); c) creating a first voltage gradient between said sample electrode and said drain electrode, such that the charged components move into said separation channel and become stacked within a region of said separation channel (Claim 1, step (b); Claim 6, lines 25-28); and d) creating a second voltage gradient between said downstream and upstream electrodes, such that the charged components move through the separation channel and separate into discrete bands according to their electrophoretic mobilities. (Claim 1, step (d); Claim 6, lines 25-28)

Claim 6 of Application No. 09/780,638 does not explicitly disclose: both the first and second electrolyte solutions each comprising an ion having lower mobility in an electric field than any of said charged components; or placing at least one of said sample and drain electrodes in a floating state during the electrophoretic separation. (Step (d) of the instant claim)

Křivánková et al disclose an analogous isotachophoretic stacking method in which both first and second electrolyte solutions comprise the lower-mobility ion. (Figure 24, ion B) They also disclose electrolytes and concentrations corresponding to instant claims 14-24, as discussed above in paragraph 6.

Manz et al disclose placing at least one of said sample and drain electrodes in a floating state concurrently with application of the potential between upstream and downstream electrodes. (Column 5, lines 48-58) They also disclose electrode activation steps and device geometry corresponding to instant claims 2-8, as discussed above in paragraph 6.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of claim 6 in Application 09/780,638 by including the low-mobility ion in the sample electrolyte mixture, as taught by Křivánková et al, because it would allow use of aliquots of the same sample mixture in analyses involving different stacking methods (i.e. low vs. high mobility ions present in the background electrolyte)

Additionally, with the presence of the background electrolyte through all channels prior to sample injection, unavoidable diffusion will lead to some presence of the low-mobility ion in the both the sample and background electrolytes.

It would also have been obvious to allow the electrodes in the sample and waste reservoirs to float after injection, as taught by Manz et al, because it provides the simplest method of injection. Additionally, with the staggered side channel geometry, it would also be obvious to allow the downstream side channels to float at least until the upstream end of the sample plug migrates past them, because there is no need to prevent sample diffusion into the sample plug itself. See the treatment of claim 3 in Paragraph 6 above.

Other modifications to device geometry, electrode activation sequence and steps, and electrolyte composition and concentration, as taught by Manz et al and Křivánková et al, would be obvious as discussed above in paragraph 6.

This is a provisional obviousness-type double patenting rejection.

11. Claims 9-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of copending Application No. 09/780,638 in view of Křivánková et al and Manz et al as applied to claim 1 above and further in view of Ramsey. (US 6,342,142).

Claim 6 of Application No. 09/780,638, Manz et al, and Křivánková et al disclose a combined method as described above in addressing claim 1.

The claimed material not explicitly disclosed by Claim 6 of Application No. 09/780,638, Manz et al, and Křivánková et al; the material disclosed by Ramsey; and the motivations for combining the methods are exactly as stated above in paragraph 7.

This is a provisional obviousness-type double patenting rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Benvegna et al disclose related injection methods.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

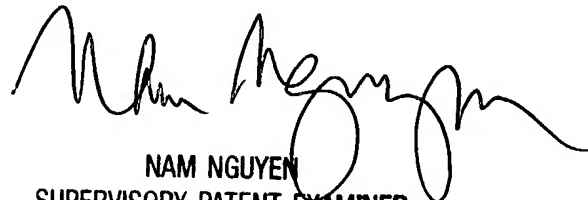
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JTB

September 14, 2004



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